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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/752,342 | WYNNE ET AL. | |
| | Examiner | Art Unit | |
| | Susannah Lee | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's Remarks filed on 3/11/05.
2. ☒ The allowed claim(s) is/are 1-15 and 21 renumbered as 1-16.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>033005</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Claims 1-21 are pending in this application. Claims 22-39 were canceled by supplemental amendment.

Response to Amendment/Remarks

Applicant's supplemental amendment filed on 03/11/2005 is acknowledged.

Applicant's remarks, see pages 7-11, filed 03/11/2005, with respect to Claims 1-14 have been fully considered and are persuasive. The rejections of Claims 1-14 have been withdrawn.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Shu Lee on 03/29/2005.

The application has been amended as follows:

In Claim 14, p. 5, line 19, insert the word ---and--- after the semicolon at the end of the line.

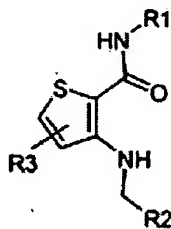
In Claim 15, p. 5, line 3, insert ---wherein the hyperproliferative disorder is selected from the group consisting of breast cancer, head cancer, neck cancer, gastrointestinal cancer, leukemia, ovarian, bronchial, lung or pancreatic cancer--- at the end of the sentence after the phrase claim 1.

Delete Claims 16-20.

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Reasons for Allowance

The present invention is directed to (2-carboxamido)-3-aminothiophene compounds as

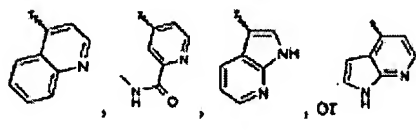
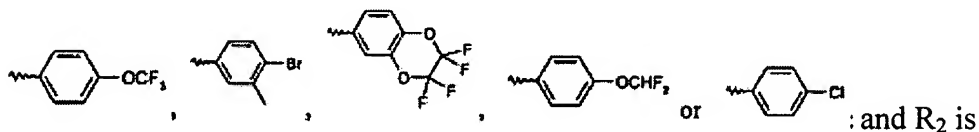


depicted in the compound of formula (I),

. The closest prior art of record is

Wood et al. (U.S. Pat. Num. 6,187,799), which teaches similar 3-aminothiophene compounds.

The difference is that in the instant application, R1 is



, which are not taught by the prior art. Therefore, since the

prior art does not teach or suggest the instant invention it is allowed.

In addition the present invention is directed to inhibiting c-Kit proto-oncogene using the compound of formula (I). Support for this is found in Applicant's specification and the non-patent literature applicant provided. In addition, the following journal articles provide support for applicant's intended use:

Sihto, Harri et al., "KIT and Platelet-Derived Growth Factor Receptor Alpha Tyrosine Kinase Gene Mutations and KIT Amplifications in Human Solid Tumors," Journal of Clinical Oncology, Volume 23(1), 2005, pp. 49-57.

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Potti, Anil et al., "Immunohistochemical Determination of HER-2/neu Overexpression in Malignant Melanoma Reveals No Prognostic Value, while c-KIT Overexpression Exhibits Potential Therapeutic Implications," Journal of Carcinogenesis, Volume 2(8), 2003.

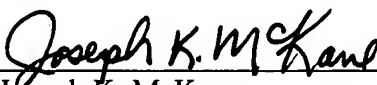
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Lee whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Lee
Patent Examiner, AU 1626


Joseph K. McKane
Supervisory Patent Examiner
AU 1626
Date: 03/31/05